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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,019	09/30/2003	Mauricio Rodolfo Carrasco	026254-00017	4530
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EXAMINER REIMERS, ANNETTE R				
ART UNIT		PAPER NUMBER		
3733				

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/674,019	CARRASCO, MAURICIO RODOLFO	
	<b>Examiner</b>	<b>Art Unit</b>	
	Annette R. Reimers	3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 and 17 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/16/04</u> .  | 6) <input type="checkbox"/> Other: ____                                     |

## DETAILED ACTION

### *Specification*

The abstract of the disclosure is objected to because it includes phrases, which can be implied, e.g. "This invention relates to".

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement.

Applicant is further reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The specification is further objected to as failing to comply with 37 CFR 1.84(p)(5), which states: "Reference characters not mentioned in the description shall not appear in the drawings. Reference characters mentioned in the description must appear in the drawings." Reference numbers 10, 11, 12 and 13 are not mentioned in the detailed description. Correction is required.

The specification is also objected to because of the following informalities: There appear to be several typographical errors throughout the specification, e.g. "Likewise",

on page 3, line 15 and "Intebdy", on page 12, line 20. Appropriate correction is required.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: If the applicant wants the lateral view to be the preferred configuration then this should be explained in claim 1 rather than placing the words "lateral view" in parenthesis, e.g. a lateral view configuration.

Claim 2 is objected to because of the following informalities: If the applicant wants the implant to be curved then this should be explained in claim 2 rather than placing the word "curved" in parenthesis.

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 appears to be a dependent claim, however, it does not specify the parent claim. Claim 5 will be considered to depend from claim 1 for examination purposes.

Claim 5 is further objected to because of the following informalities: If the applicant wants the implant to be curved then this should be explained in claim 5 rather than placing the word "curved" in parenthesis.

Claim 16 is objected to because of the following informalities: If the applicant wants the lateral view to be the preferred configuration then this should be explained in

claim 16 rather than placing the words "lateral view" in parenthesis, e.g. a lateral view configuration.

Claim 16 is objected to because of the following informalities: If the applicant wants the implant to be curved then this should be explained in claim 16 rather than placing the word "curved" in parenthesis.

Claims 1-25 are objected to because of the following informalities: There appear to be several typographical errors throughout the claims, e.g. "osteosynhtesis", of claim 8, line 14, and "inlcudes", of claim 16, line 10. Appropriate correction is required.

Claims 1-25 are further objected to because of the following informalities: The word "it" and "its" need to be defined.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6-7, 13 and 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, line 2, the word "being" lacks proper antecedent basis.

In claim 5, line 9, the word "being" lacks proper antecedent basis.

In claim 6, line 2, the word "opening" lacks proper antecedent basis.

In claim 7, line 2, "hole" lacks proper antecedent basis.

In claim 7, line 2, "the area" lacks proper antecedent basis.

In claim 13, the phrases "preferably", "more preferably", and "most preferably" render the claim indefinite because it is unclear what the limitations, if any, such places on the claimed invention. See MPEP § 2173.05(d).

In claim 16, line 11, the word "being" lacks proper antecedent basis.

In claim 17, line 2, the word "opening" lacks proper antecedent basis.

In claim 18, line 2, "hole" lacks proper antecedent basis.

In claim 18, line 2, "the area" lacks proper antecedent basis.

In claim 19, the phrases "preferably", "more preferably", and "most preferably" render the claim indefinite because it is unclear what the limitations, if any, such places on the claimed invention. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15-19, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (US Patent Number 6,080,158).

Lin discloses an implant to be inserted in the disc space between two adjacent vertebrae for the correction of the vertebral spine curvature, wherein the implant's lateral view configuration is a wedge or acute-angled isosceles trapeze, wherein the area opposite the shorter base or opposite to the vertex is a rounded pyramid-like surface capable of being laterally shifted to one side, and the upper and lower surfaces

of the trapeze include saw-shaped protuberances, 121, extended along the width of the upper and lower surfaces and oriented to prevent horizontal slipping in the direction of the anterior portion of the vertebrae, and wherein the protuberances are capable of penetrating to the vertebral plates of the adjacent vertebrae (see figures 1, 2, 5B and 5C). The implant has a hollow volume inside and holes, 110, in its surfaces that communicate with the hollow volume, are capable of receiving osteosynthesis material, and enable and facilitate the osteosynthesis (see figures 1 and 2). Furthermore, the implant includes hollow tunnel-shaped cavities in the posterior and lateral surfaces, 141 and 111, respectively, for the insertion of tools suitable for handling the implant through a posterior or a lateral access (see figure 2). Regarding method claims 8-12 and 25, the implant device of Lin is inherently capable of performing the method for producing an increase in the vertebral spine curvature (see figures 5A, 5B, 5C and 6).

Claims 1-9, 11-12, 15-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Marino (US Patent Number 6,290,724).

Marino discloses an implant to be inserted in the disc space between two adjacent vertebrae for the correction of the vertebral spine curvature, wherein the implant's lateral view configuration is a wedge or acute-angled isosceles trapeze, wherein the area opposite the shorter base or opposite to the vertex is a rounded pyramid-like surface capable of being laterally shifted to one side, and the upper and lower surfaces of the trapeze include saw-shaped protuberances, 36, extended along the width of the upper and lower surfaces and oriented to prevent horizontal slipping in the direction of the anterior portion of the vertebrae, and wherein the protuberances are

capable of penetrating to the vertebral plates of the adjacent vertebrae (see figure 18). The implant has a hollow volume inside and holes in its surfaces that communicate with the hollow volume, are capable of receiving osteosynthesis material, and enable and facilitate the osteosynthesis (see figures 19, 20 and 22). Furthermore, the implant includes hollow tunnel-shaped cavities in the posterior and lateral surfaces for the insertion of tools suitable for handling the implant through a posterior or a lateral access (see figures 19, 20 and 22). Regarding method claims 8-9, 11 and 12, the implant device of Marino is capable of performing the method for producing an increase in the vertebral spine curvature (see figures 25-31).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 14, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (US Patent Number 6,080,158).

Lin discloses the claimed invention except for the angle formed by the upper and lower surfaces being at least 10 degrees, the length being no greater than 20 mm, the minimum height being 8 mm and the maximum height being 30 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant device of Lin with the angle formed by the upper and lower surfaces being at least 10 degrees, the length being no greater than 20 mm, the

minimum height being 8 mm and the maximum height being 30 mm., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 22-24, Lin discloses the claimed invention except for the angle formed by the upper and lower surfaces being 18 degrees, the angle formed by the upper and lower surfaces being 29 degrees, and the angle formed by the upper and lower surfaces being 47 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant device of Lin with the angle formed by the upper and lower surfaces being 18 degrees, the angle formed by the upper and lower surfaces being 29 degrees, and the angle formed by the upper and lower surfaces being 47 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 13, 14, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino (US Patent Number 6,290,724).

Marino discloses the claimed invention except for the angle formed by the upper and lower surfaces being at least 10 degrees, the length being no greater than 20 mm, the minimum height being 8 mm and the maximum height being 30 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant device of Marino with the angle formed by the upper and lower surfaces being at least 10 degrees, the length being no greater than 20 mm, the

minimum height being 8 mm and the maximum height being 30 mm., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 22-24, Marino discloses the claimed invention except for the angle formed by the upper and lower surfaces being 18 degrees, the angle formed by the upper and lower surfaces being 29 degrees, and the angle formed by the upper and lower surfaces being 47 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant device of Marino with the angle formed by the upper and lower surfaces being 18 degrees, the angle formed by the upper and lower surfaces being 29 degrees, and the angle formed by the upper and lower surfaces being 47 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 10 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino (US Patent Number 6,290,724) in view of Lin (US Patent Number 6,080,158).

The Marino implant device is capable of performing the method for producing an increase in the vertebral spine curvature except for the step of using pedicular screws as an external fixation means, fixing the screws to bars or plates, and immobilizing the assembly with nuts or other fixation means. Lin discloses an implant device that includes the method of using screws as an external fixation means, wherein the screws

are fixed to plates and the assembly is immobilized with nuts (see Figure 6). Lin teaches the use of screws as an external fixation means, wherein the screws are fixed to plates and the assembly is immobilized with nuts, in order to provide further stabilization (see figure 6 and column 3, lines 36-39). It would have been obvious to one skilled in the art at the time the invention was made to incorporate the use of a fixation and immobilization means with the implant device of Marino, in view of Lin, in order to provide further stabilization.

#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR



EDUARDO C. ROBERT  
PRIMARY EXAMINER